Remarks

Claims 1-20 and 25-37 are pending in this application, and subject to a Restriction Requirement. Claims 2, 7, and 27 are amended herein. Claims 2 and 27 are amended to correct matters of form. Claim 7 is amended to correct a minor grammatical error. After entry of this document, **claims 1-20 and 25-37 are pending** and ready for substantive examination.

Restriction Requirement

Claims 1-20 and 25-37 of this §371 National Stage application were indicated as being subject to a restriction requirement. In particular, the following Groups have been designated:

Group I.	Claims 1-7 and 25, drawn to a polypeptide, antigenic fragment, and pharmaceutical composition;
Group II.	Claims 8-20 and 26, drawn to an isolated nucleic acid, vector, host cell, and pharmaceutical composition;
Group III.	Claims 27-34, drawn to a method for inducing an immune response to a *P. ariasi* in a subject; and
Group IV.	Claims 35-37, drawn to a method for inhibiting a symptom of a *Leishmania* infection or preventing a *Leishmania* infection in a subject.

The Office action states that "Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features…" The Office action alleges that the Groups have different special technical features, namely a purified salivary *P. ariasi* polypeptide (Group I); an isolated nucleic acid, vector, host cell (Group II); and methods of use of the first technical feature (a purified salivary *P. ariasi* polypeptide) (Groups III and IV). The Office action therefore concludes that "Groups II-IV lack[s] unity with Group I because they do not have the same technical feature."

Applicants respectfully disagree and submit that all of Groups I-IV do in fact relate to a single special technical feature, which feature makes a contribution over the prior art. As such, all of the claims should be examined together. Applicant requests that the requirement be withdrawn in light of the arguments herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a national stage application such as this; unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a), emphasis added.]

This makes it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are linked to form a single inventive concept? If there is, then one asks does that special technical feature **define a contribution over the prior art** for each of the claimed inventions? If no relevant prior art is identified, then there can be no finding of lack of unity.

Applying the Standard in the Current Case

Groups I through IV are linked to form a single general inventive concept. The invention as claimed relates to a substantially purified salivary *P. ariasi* polypeptide (Group I). The claimed invention further relates to nucleic acid sequences encoding the substantially purified salivary *P. ariasi* polypeptide (Group II), and methods of using the substantially purified salivary *P. ariasi* polypeptide (Groups III and IV). Thus, the special technical feature shared among all of the claims is the **substantially purified salivary *P. ariasi* polypeptide**. Moreover, as claims 1-20 and 25-37 (Groups I-IV) all depend, directly or indirectly, from claim 1 (thereby incorporating all of the limitations thereof), these claims all relate to the special technical feature of the substantially purified salivary *P. ariasi* polypeptide of claim 1.

Furthermore, this special technical feature does define a contribution over the prior art for each of the claimed inventions. There is no reference of record in the case that reads on the

substantially purified salivary *P. ariasi* polypeptide, or its use. No reference has been cited in the current Restriction Requirement, which would appear to be a clear admission that there is no relevant prior art.

Since the Office has provided neither allegation nor evidence that a substantially purified salivary *P. ariasi* polypeptide is disclosed or rendered obvious by the prior art, this feature clearly constitutes an appropriate "corresponding special technical feature" sufficient for the fulfillment of the unity of invention requirement. [*See* 37 CFR § 1.475(a); MPEP § 1893.03(d).]

In summary, as required by 37 CFR §1.475, the claims pending in the application have unity of invention because they are directed "to a group of inventions so linked as to form a single general inventive concept" because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature[]" – **a substantially purified salivary *P. ariasi* polypeptide** – and this special technical feature "define[s] a contribution . . . over the prior art."

As unity of invention exists among all of the Groups in the present application, Applicants submit that it is inappropriate to subject the claims to a requirement for restriction. In addition, Applicants note that the MPEP states that "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention" (see "Unity of Invention", Section (c)(i), Annex B to the Administrative Instructions under the PCT, MPEP). Claims 2-20 and 25-37 depend, directly or indirectly, from claim 1. Thus, if claim 1 is allowed, Applicants respectfully request that all of the claims, and all of the sequences recited in these claims, be examined in the current case.

Election

Under protest, and only to comply with 37 CFR §1.499, Applicants hereby provisionally elect Group I (directed to claims 1-7 and 25), drawn to a polypeptide, antigenic fragment, and

pharmaceutical composition. In addition, Applicants further elect a single *P. ariasi* amino acid sequence (SEQ ID NO: 11).

Finally, in the unlikely event that the Office determines that all of the Groups (and sequences) cannot be recombined, Applicants request that the claims of Group IV, directed to the method of inhibiting a symptom of a *Leishmania* infection or preventing a *Leishmania* infection in a subject using the polypeptide as set forth in SEQ ID NO: 11, be examined with the claims of Group I (directed to the polypeptide). The method claims depend from or otherwise include all the limitations of claims to the product. Applicants expressly request that the method claims be rejoined and the claims examined, at the latest upon the allowance of any of the product claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600.

Conclusion

It is believed that the application is in condition for substantive examination. If any minor matters remain to be addressed prior to examination, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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